

**UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION**

TRUTEK CORP.,

Plaintiff,

v.

Case No. 2:21-cv-10312

BLUEWILLOW BIOLOGICS, INC.;
ROBIN ROE 1 through 10, gender
neutral fictitious names; and ABC
CORPORATION 1 through 10 (fictitious
names).

Hon. F. Kay Behm

Defendants.

**DEFENDANT/COUNTER-PLAINTIFF BLUEWILLOW BIOLOGICS,
INC.'S BRIEF REGARDING MOOTNESS OF CASE**

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I. INTRODUCTION

Defendant BlueWillow Biologics, Inc. respectfully submits that this case should be dismissed with prejudice as Trutek Corp. no longer has standing to maintain the action. The Court has determined that Trutek is not entitled to recover any damages even if it were to successfully prove that the only accused product – NanoBio[®] Protect – has infringed at least one valid claim of the asserted patent. BlueWillow has already permanently removed NanoBio[®] Protect from the market and offered to stipulate to do the same in the future. As there is no ongoing injury to Trutek, and Trutek is not entitled to a remedy for any past injury, the infringement claim raised in this action is no longer redressable and Trutek lacks standing to maintain suit. To the extent Trutek argues that it is nonetheless entitled to declaratory relief, any such claim for declaratory judgment of infringement would be improper. Not only has Trutek failed to plead a claim for declaratory relief, it seeks declaratory relief for improper reasons, namely for use in speculative, as-yet unfiled lawsuits related to activity the Court has already found exempt from infringement under the safe harbor of 35 U.S.C. § 271(e)(1). Because there is no remedy the Court can award to Trutek in this action under any theory, its case must be dismissed with prejudice.

II. FACTUAL BACKGROUND

On February 10, 2021, Trutek filed suit alleging infringement of U.S. Patent No. 8,163,802 (the “’802 patent”) patent against BlueWillow. The complaint identifies a single accused product, NanoBio[®] Protect. ECF 9, Counterclaim ¶ 6; ECF 1. Specifically, Trutek sought damages and an injunction preventing the further manufacture and sale of NanoBio[®] Protect. ECF 1. BlueWillow filed an answer and counterclaim, asserting defenses of non-infringement and invalidity of the ’802 patent. ECF 9. Despite initiating the lawsuit, Trutek failed to engage in meaningful discovery. ECF 30 at 10-12.

On May 11, 2022, Trutek filed a Motion for Leave to Amend the Complaint, seeking to add infringement claims directed to BlueWillow’s developmental vaccines. ECF 28 at 9; ECF 28-4, ¶¶ 25-44. BlueWillow opposed the motion, noting in part that the proposed amendment was futile because the accused developmental vaccine activity was covered by the safe harbor of 35 U.S.C. § 271(e)(1). ECF 30 at 18-25. The Court agreed, concluding that the “vaccines plainly fall into the safe harbor provision” and denied Trutek’s motion. ECF 32 at 3. As such, discovery in this case has been limited to NanoBio[®] Protect, the only accused product.

BlueWillow subsequently filed a motion *in limine* to exclude Trutek’s damages-related theories and evidence (ECF 39) and a motion for summary judgment of no remedy (ECF 59). In its decision, the Court noted that Trutek had

failed to disclose any damages-related theories or evidence and granted in part BlueWillow's motion *in limine*, precluding Trutek from relying on undisclosed damages evidence, including unidentified testimony from unidentified damages witnesses, in support of undisclosed damages theories. ECF 84 at 34-35. The Court further held that, "[g]iven the extent of non-disclosure, the Court's exclusion effectively precludes Trutek from seeking damages." *Id.* at 35. In turn, the Court granted summary judgment of no damages in favor of BlueWillow. *Id.* at 40.

Pursuant to the Court's order, the parties met and conferred about whether there were any remaining issues in view of the summary judgment order. The parties were unable to reach agreement and accordingly, the Special Master requested additional briefing about whether the case is moot given the Court's order granting summary judgment of no damages and the fact that BlueWillow is willing to stipulate to not selling the accused NanoBio[®] Protect product in the future.

III. LEGAL STANDARD

Article III of the Constitution grants the courts the ability to adjudicate cases and controversies arising under the laws of the United States. U.S. CONST. art. III, § 2; *NRA of Am. v. Magaw*, 132 F.3d 272, 279 (6th Cir. 1997). Determining whether there is an actual case or controversy is analyzed, at least, through the lens of standing, justiciability and mootness. There must be a "real and substantial controversy admitting of specific relief through a decree of a conclusive character,

as distinguished from an opinion advising what the law would be upon a hypothetical state of facts.” *NRA*, 132 F.3d at 279-80 (quoting *Aetna Life Ins. Co. v. Haworth*, 300 U.S. 227, 240-41 (1937)). Standing contains three elements: (1) “an injury in fact . . . which is (a) concrete and particularized . . . and (b) actual or imminent, not conjectural or hypothetical”; (2) “a causal connection between the injury and the conduct complained of”; and (3) “it must be likely, as opposed to merely speculative, that the injury will be redressed by a favorable decision.” *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560-61 (1992). Standing must be maintained for each claim and form of relief sought throughout the litigation. *Davis v. Federal Election Comm’n*, 554 U.S. 724, 732-34 (2008). Article III also requires cases to be ripe for adjudication. “Ripeness separates those matters that are premature because the injury is speculative and may never occur from those that are appropriate for the court’s review.” *NRA*, 132 F.3d at 280.

A case is no longer a controversy, and becomes moot, “when the issues presented are no longer ‘live’ or the parties lack a legally cognizable interest in the outcome,” namely, the injury is no longer redressable. *Murphy v. Hunt*, 455 U.S. 478, 481 (1982) (citations omitted); *see also Already, LLC v. Nike, Inc.*, 568 U.S. 85, 90-91 (2013); *Cleveland Branch, N.A.A.C.P. v. City of Parma, OH*, 263 F.3d 513, 530-31 (6th Cir. 2001); *Sierra Club v. U.S. Fish & Wildlife Serv.*, 189 F. Supp. 2d 684, 693 (W.D. Mich. 2002) (“[F]ederal courts cannot issue declaratory or

injunctive relief as to moot cases.”). While a defendant’s voluntary cessation of the alleged wrongful behavior does not automatically deprive a court of the ability to hear the case, “[a] case might become moot if subsequent events [make] it absolutely clear that the allegedly wrongful behavior could not reasonably be expected to recur.” *Friends of the Earth, Inc. v. Laidlaw Env’t Servs. (TOC), Inc.*, 528 U.S. 167, 189 (2000) (citations omitted) (emphasis added). For instance, a case might be moot when a party issues a covenant not to engage in the wrongful behavior, *see Already*, 568 U.S. at 100, or disavows any appeal of an unfavorable decision, *see ABS Global, Inc. v. Cytonome/ST, LLC*, 984 F.3d 1017, 1022-23 (Fed. Cir. 2021).

IV. ARGUMENT

In its complaint, Trutek raised allegations of infringement against a single product (NanoBio® Protect) and requested two forms of relief – damages and an injunction. Trutek unsuccessfully tried to expand the scope of the instant action by adding infringement claims against BlueWillow’s developmental vaccine products. The Court denied Trutek’s request, finding the vaccines exempt from infringement under the safe harbor. As such, Trutek’s claims, and the relief that it can obtain through this action on those claims, is necessarily limited to NanoBio® Protect.

The Court has already ruled on summary judgment that Trutek is not entitled to recover any damages for the asserted infringement by NanoBio® Protect. Trutek’s request for injunctive relief is likewise moot in view of the undisputed facts that

NanoBio® Protect is no longer sold and BlueWillow has agreed to not make or sell the product in the future. Because there is no relief that the Court can award to Trutek in this case, it lacks standing and the case should be dismissed with prejudice.

Despite the fact there is no remedy available to Trutek, it nonetheless asserts that it is entitled to a declaratory judgment that NanoBio® Protect infringes the '802 patent. While Trutek never pled a claim for declaratory relief, its argument falls short for several additional reasons. More specifically, even if the Court had jurisdiction to issue declaratory relief (it does not), the Court nevertheless has significant discretion to decide whether to exercise that discretion. Trutek's sole argument for the relevance of any such declaratory relief is highly speculative, relating to its potential impact on a future lawsuit directed to the developmental vaccines that may never even materialize, and represents nothing more than an attempt to circumvent the Court's prior decision finding that activity protected under the safe harbor. Likewise, the exercise of declaratory judgment jurisdiction in this circumstance would run afoul of the very reasons why Congress enacted the safe harbor provision.

As such, this case should be dismissed with prejudice because Trutek's only remaining form of relief is moot, it lacks standing to maintain the case, and any

discretionary declaratory relief is inappropriate.¹

A. Relief in this Case Must Be Limited to NanoBio[®] Protect

As explained in Section II, *supra*, there is only one accused product in this case, NanoBio[®] Protect. Trutek has already tried, and failed, to add allegations directed to BlueWillow's developmental vaccine products. Notably, Trutek's motion for leave was not denied on procedural grounds, but based on the substantive finding that "Defendant's vaccines are protected under the safe harbor provision of 35 U.S.C. § 271(e)(1)." ECF 32 at 2; 35 U.S.C. § 271(e)(1) ("It shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention . . . solely for uses reasonably related to the development and submission of information under a Federal Law which regulates the manufacture, use, or sale of drugs or veterinary biological products.").

Consistent with the Court's ruling that the vaccine products are exempt from infringement claims, fact and expert discovery in this case was likewise limited to Trutek's claims of infringement directed to NanoBio[®] Protect. It necessarily follows

¹ Dismissal with prejudice is appropriate to prevent Trutek from refileing to fix the many mistakes and discovery failures that led up to the summary judgment decision and supplemental briefing. *Apple, Inc. v. Motorola, Inc.*, 869 F. Supp. 2d 901, 924 (N.D. Ill. 2012), *rev'd on other grounds* (dismissing case with prejudice, noting that it "would be ridiculous to dismiss a suit for failure to prove damages and allow the plaintiff to refile the suit so that he could have a second chance to prove damages").

that the only relief that can be awarded to Trutek on the claims asserted in its Complaint is likewise limited to relief directed to NanoBio[®] Protect. *See Microsoft Corp. v. DataTern, Inc.*, 755 F.3d 899, 911 (Fed. Cir. 2014) (stating the issues and products actually litigated define the scope of judgment). To the extent Trutek requests relief that is targeted to any other product, including BlueWillow's developmental vaccines, it must be denied.

B. Trutek's Request for Injunctive Relief Is Moot

The parties do not dispute that NanoBio[®] Protect is no longer sold and has not been sold since shortly after this case was filed. ECF 28 at 8; 28-1 at ¶ 7. BlueWillow has further offered to execute a stipulation agreeing not to make, use, sell, offer to sell, or import NanoBio[®] Protect at any time in the future. As such, Trutek's request for an injunction to prohibit the allegedly infringing activity defined by the operative pleading, *i.e.*, the ongoing sale of NanoBio[®] Protect should it be found to infringe a valid claim of the '802 patent, is moot. To the extent Trutek argues that any injunctive relief should extend to other activity by BlueWillow beyond the sale of NanoBio[®] Protect, such request is improper for the reasons stated above.

“When a ‘party relies on potential infringement liability as a basis for injury in fact, but is not currently engaging in infringing activity,’ our Article III standing cases explain that the party ‘must establish that it has concrete plans for future activity that creates a substantial risk of future infringement or [will] likely cause the

patentee to assert a claim of infringement.” *ABS Global*, 984 F.3d at 1023 (citing *JTEKT Corp. v. GKN Auto. Ltd.*, 898 F.3d 1217, 1221 (Fed. Cir. 2018)). A claim is moot when “subsequent events [make] it absolutely clear that the allegedly wrongful behavior could not reasonably be expected to recur.” *Laidlaw*, 528 U.S. at 189.

BlueWillow is not engaging in any allegedly infringing activity that is before the Court at this time. It no longer makes or sells the only accused product, and the Court has ruled that the developmental vaccines are exempt from infringement under the safe harbor. And, by offering to stipulate to not make or sell NanoBio[®] Protect in the future, BlueWillow has demonstrated that the “allegedly wrongful behavior” is not “reasonably ... expected to recur.” *Id.* Indeed, Trutek cannot identify any plans of BlueWillow’s to resume selling NanoBio[®] Protect because no such plans exist. There is nothing that would likely cause Trutek to assert another claim of infringement against NanoBio[®] Protect. As there is no basis for injury, under Article III, Trutek’s claim for injunctive relief must be dismissed as moot.

C. Trutek Lacks Standing to Maintain the Case, Which Must Be Dismissed

To maintain standing, Trutek must prove an injury in fact, a causal connection between the injury and BlueWillow’s conduct, and a likelihood the injury will be redressed by a favorable decision. *See Lujan*, 504 U.S. at 560-61. Trutek asked for (1) damages and (2) an injunction prohibiting BlueWillow from manufacturing or

selling, inducing others to sell, and exporting NanoBio[®] Protect. ECF 1 at 7-8.² “Relief that does not remedy the injury suffered cannot bootstrap a plaintiff into federal court; that is the very essence of the redressability requirement.” *Steel Co. v. Citizens for a Better Env’t*, 523 U.S. 83, 107 (1998) (dismissing complaint).

The Court has already ruled that Trutek is not entitled to damages, including pre-suit damages. ECF 84. Thus, there is no monetary relief that might be granted to redress any alleged injury. *See American Piledriving Equip., Inc. v. Hammer & Steel, Inc.*, No. 4:11cv811 CDP, 2012 WL 1414837, at *3 (E.D. Mo. Apr. 24, 2012) (finding that, as the plaintiff could not establish entitlement to damages, there was no redress that could be provided by a favorable decision from the court).

The only remaining remedy that could potentially be awarded to Trutek is its request for injunctive relief directed to NanoBio[®] Protect. However, as established in Section B, *supra*, an injunction directed to NanoBio[®] Protect could not and would not remedy any injury suffered by Trutek. BlueWillow has already stopped selling NanoBio[®] Protect and has agreed that it will not make or sell the product in the future. As such, there is no ongoing injury to Trutek that injunctive relief could redress. Here, as in *Steel Co.*, because none of the relief sought by Trutek would

² Trutek also requested “other such and further relief as the Court may deem to be just and proper.” ECF 1 at 8. There is no other relief to which Trutek is entitled.

likely remedy its alleged injury in fact, Trutek lacks standing to maintain this suit. 523 U.S. at 109-10. Thus, it must be dismissed with prejudice.

D. The Court Should Decline to Consider Trutek's Untimely and Speculative Request for Declaratory Relief

Upon realizing that it cannot recover any remedy based on its allegations of infringement directed to NanoBio[®] Protect, Trutek now argues for the first time there is an open question of declaratory relief on the issue of infringement of NanoBio[®] Protect.³ More specifically, Trutek argues that a declaration of infringement with respect to NanoBio[®] Protect may be relevant in the future because of the potential preclusive effect such a decision may have on whether BlueWillow's vaccine products infringe, if they are ever approved and commercialized. Trutek has not articulated any other rationale for the potential relevance of such declaratory relief.

³ During the meet and confer, Trutek also stated it seeks a "declaration of patent validity." Not only did Trutek not request this relief in the complaint, but the Court cannot issue such a declaration. Patent validity is tied to BlueWillow's defense of invalidity and thus, the Court can only decide whether BlueWillow met its burden of proving the '802 patent invalid. *Panduit Corp. v. Dennison Mfg. Co.*, 774 F.2d 1082, 1096 (Fed. Cir. 1985) ("The role of the court is to determine whether the validity challenger carried [their] burden" and "[i]t is not, therefore, a required role of a court, in a suit for patent infringement, to declare patents valid.") (vacated on other grounds); *see also Semiconductor Energy Lab. Co. v. Nagata*, 706 F.3d 1365, 1370 (Fed. Cir. 2013) ("The relief requested by [plaintiff] is akin to seeking a declaratory judgment of patent validity, which is not a viable cause of action").

Like the remainder of Trutek’s assertions, there is no basis in law or fact for Trutek’s new and highly speculative argument. As a threshold matter, Trutek did not plead any claim for declaratory judgment and did not assert jurisdiction under 28 U.S.C. § 2201(a). Dkt. 1 at 1-2, 7-8. Further, even assuming Trutek did properly plead a claim for declaratory judgment, as established in Sections B-C, *supra*, there is no “actual controversy” between the parties with respect to the product at issue, and therefore, declaratory relief is not available. *See MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 127 (2007) (“Basically, the question in each case is whether the facts alleged, under all the circumstances, show that there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.”) (citing *Maryland Casualty Co. v. Pacific Coal & Oil Co.*, 312 U.S. 273 (1941)); *see also Apple*, 869 F. Supp. 2d at 923-24 (“[W]hen the court has determined that neither party could obtain monetary or injunctive relief against the other, as in this case, a declaratory judgment in favor of either party would confer no tangible benefit on the victor and so there would be no federal subject-matter jurisdiction.”); *Sierra Club*, 189 F. Supp. 2d at 693 (“[F]ederal courts cannot issue declaratory or injunctive relief as to moot cases.”). Declaratory judgment jurisdiction is not appropriate with respect to the vaccine products either, as such a decision would merely be “an opinion advising

what the law would be upon a hypothetical state of facts.” *See Olin Corp. v. Consol. Aluminum Corp.*, 5 F.3d 10, 17 (2d Cir. 1993); *see also NRA*, 132 F.3d at 279-80.

Even if the Court overlooks Trutek’s pleading deficiencies and decides there is an actual controversy that warrants consideration of the request for declaratory relief, the Court has wide discretion to exercise that discretion and should not do so here for several reasons. “Since its inception, the Declaratory Judgment Act has been understood to confer on federal courts unique and substantial discretion in deciding whether to declare the rights of litigants.” *Wilton v. Seven Falls Co.*, 515 U.S. 277, 287 (1995); *see also* 28 U.S.C. § 2201(a) (a court “may declare the rights and other legal relations of any interested party seeking such declaration”) (emphasis added). In other words, declaratory jurisdiction is not automatic or obligatory. *Id.* at 288.

Courts routinely decline to exercise discretion to hear claims of declaratory relief directed to questions of past infringement where the patent owner is not entitled to recover damages and the only purpose for the declaratory judgment would be to use it offensively against new parties or in future proceedings. *American Piledriving*, 2012 WL 1414837 at *3. Declaratory judgment is not the appropriate tool for “determining rights and defenses available . . . in future proceedings.” *Williams v. BASF Catalysts LLC*, 765 F.3d 306, 327-28 (3rd Cir. 2014); *see also Serco Services Co., L.P. v. Kelley Co., Inc.*, 51 F.3d 1037, 1039-40 (Fed. Cir. 1995) (upholding dismissal of claim for declaratory judgment because action was brought

in anticipation of future infringement suit and the venue for that suit was more convenient for witness and document location).

Here, as in *American Piledriving*, Trutek is not entitled to recover damages (ECF 84). Instead, Trutek seeks declaratory judgment solely for its own benefit to use in a potential future lawsuit directed to other products. Trutek's rationale is highly speculative, premature and not ripe for adjudication at this stage. BlueWillow may never engage in any activity that falls outside of the safe harbor, and as such, no court will ever have jurisdiction to hear infringement claims directed to the developmental vaccine products. Because any such future case would necessarily involve different products that were not the subject of discovery in the instant case, such future case is the only correct time and place to determine the rights and remedies that may be available to Trutek for that separate cause of action.

Finally, the Court has already considered whether claims directed to the developmental vaccine products belong in the instant case and squarely decided "no." ECF 32. Trutek's last-ditch argument that a declaration of infringement as to NanoBio[®] Protect might be relevant to whether the developmental vaccine products infringe is nothing more than a back-handed attempt by Trutek to evade this Court's prior decision on the safe harbor. Moreover, courts have expressly recognized that declaratory judgment actions directed to developmental drugs protected by the safe harbor are especially disfavored as it would "discourage and hamper the very efforts

that Congress sought to stimulate” with the safe harbor provision. *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 3 F. Supp. 2d 104, 112-13 (D. Mass. 1998) (declining to exercise discretion to hear claims for declaratory relief).

For all of the foregoing reasons, the Court does not have jurisdiction to issue the declaratory relief articulated and requested by Trutek. Should the Court nevertheless decide that declaratory judgment jurisdiction exists, it should nevertheless decline to exercise its discretion to hear Trutek’s un-pled and highly speculative claims for declaratory relief under the circumstances of this case.

V. CONCLUSION

For all the reasons stated herein, BlueWillow respectfully submits that Trutek’s complaint should be dismissed with prejudice and that Trutek should not be given leave to refile.

Dated: December 1, 2023

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that, on December 1, 2023, I filed the foregoing document and this Certificate of Service with the Court using the ECF system.

/s/ Nicholas J. Ellis